

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 05 MAR 2004

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Applicant's or agent's file reference BW266R/RVP	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)
International application No. PCT/T 03/00120	International filing date (day/month/year) 03.03.2003	Priority date (day/month/year) 01.03.2002
International Patent Classification (IPC) or both national classification and IPC A01H5/00		
Applicant PLANTECHNO S.R.L. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.
 - This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
 - I Basis of the opinion
 - II Priority
 - III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV Lack of unity of invention
 - V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI Certain documents cited
 - VII Certain defects in the international application
 - VIII Certain observations on the international application

Date of submission of the demand 23.09.2003	Date of completion of this report 26.02.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Bilang, J Telephone No. +49 89 2399-8707



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No.

PCT/T 03/00120

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-29 as originally filed

Claims, Numbers

1-22 as originally filed

Drawings, Sheets

1/8-8/8 as originally filed

Sequence listing part of the description, pages:

1-9, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 the language of publication of the international application (under Rule 48.3(b)).
 the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority in written form.
 furnished subsequently to this Authority in computer readable form.
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
 the claims, Nos.:
 the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IT 03/00120

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-22
	No: Claims	
Inventive step (IS)	Yes: Claims	1-22
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IT03/00120

1. The present application discloses transformed plants capable of producing lysosomal enzymes in the seeds.
2. Reference is made to the following documents:

D1 (WO 97 10353, cited in the application) discloses the production of lysosomal enzymes in transgenic plants. The examples deal with the expression under a 35S promoter and an inducible promoter and disclose the expression in leaves. Claimed is also a method wherein a lysosomal enzyme is expressed in seeds (claim 1). Similarly, D2 (WO 02 08404) discloses the expression of lysosomal enzymes in leafs of transgenic plants, but also refers to the expression in seeds (p 61, l. 23-24).

3. However, none of these documents actually discloses the expression of lysosomal enzymes in seeds but only refer to seeds as one of a series of possible tissues. Claims 1-22 therefore can be considered to be novel over the available prior art (Article 33(2) PCT).
4. It would appear from the present application that the expression of lysosomal proteins in seeds has advantages over the expression in leaves (higher production, stability and solubility of the recombinantly expressed protein, correct glycosylation). These advantages were not derivable from the prior art which does not appear to motivate the skilled person to select seed tissue from the list provided in D1 or D2. The choice of seed as tissue for the expression of lysosomal proteins therefore was not rendered obvious by the prior art, and the subject-matter of claims 1-22 are considered to be based on an inventive activity (Article 33(3) PCT).

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